## REMARKS

Claims 1-38,41 and 43-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Claims 39, 40 and 42 are examined in the instant application.

### *Declaration under 37 CFR 1.132*

The Examiner has indicated that the declaration under 37 CFR 1.132 filed 5/5/2008 has not been considered since the declaration appeared to be an annotated draft. A new, clean copy is now attached to replace the original.

### *Information Disclosure Statement*

The Examiner has indicated that the information disclosure statement filed 5/5/2008 fails to comply with 37 CFR 1.98(a)(l), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. A replacement IDS is herein submitted.

### *Claim Objections*

The Examiner has objected to Claim 39 because of the following informalities: In line 4 it appears that Applicant, in their amendment, struck through too much language. The word "of" is now included in the claimed method.

Claims 1-38, 41 and 43-75 have now been amended to show the status identifier as "withdrawn" and not "original".

### *Claim Rejections - 35 VSC § 112*

The Examiner has maintained the rejection of claims 39, 40 and 42 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

### *Response to Arguments*

The Examiner contends that precious arguments or references have addressed how delivering an SP-C protein will treat airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an *inflammatory* response.

Applicants have shown, in the attached declaration, that surfactant proteins (SP-D SP-C, and SP-B) have been delivered intratracheally in mice; sheep and rabbits, usually mixed with carrier lipids to enhance spreading and delivery throughout the lung. Mixtures of SP-B and SP-C in lipid extracts of cow/pig lungs or surfactant isolated from lungs are routinely given for treatment of acute respiratory distress syndrome affecting pre-term infants and is a standard therapy (see Jobe, A.H. Pulmonary surfactant therapy. N. Engl. J. Med. 1993 328:861-868, 1993).

The delivery of the SP-C proteins to the lungs would be expected to act as a treatment of airway hyperresponsiveness and/or airflow limitation associated with respiratory disease involving an inflammatory response in a subject because the protein is a surface acting agent, is in direct contact with the cells in the alveoli of the lung and does not need to be effective at systemic delivery through the lung cells as with many other treatments. The present treatment with SP-C is a nonspecific treatment that will work regardless of the underlying source of inflammation. The lack of SP-C results in inflammation in mice in the absence of infection. SP-C decreases inflammation after bacterial responses and also binds endotoxins. Taken together, SP-C decreases lung inflammation.

The skilled artisan would reasonably expect, in view of the specification and the teachings in the art, that administering a SP-C therapeutic (protein) will treat airway hyperresponsiveness and/or

airflow limitation associated with a respiratory disease involving an inflammatory response. No linkage with inflammation is recited in the claimed method that would lead the skilled artisan to reasonably expect a change in inflammation that would then ultimately affect airway hyperresponsiveness and/or airflow limitation. The term "associated" is problematic with respect to the claimed method because the skilled artisan cannot determine what is the cause of airway hyperresponsiveness and/or airflow limitation which could be inflammation or another cause such as emphezema. If, as Applicants argue, inflammation is pivotal to the enablement of the claimed method of treatment, the skilled artisan would require teaching demonstrating that delivering an SP-C protein will reduce lung inflammation in a subject and further this reduction in lung inflammation is intrinsically related to airway hyperresponsiveness and/or airflow limitation and not just a mere association. What is not clear to the skilled artisan is whether airway hyperresponsiveness and/or airflow limitation is related to the respiratory disease or the inflammatory response, since again its an association. If airway hyperresponsiveness and/or airflow limitation is the result of the respiratory disease and not just an inflammatory response then the skilled artisan could not reasonably expect that by delivering an SP-C protein that airway hyperresponsiveness and/or airflow limitation will be treated. Thus for the reasons above and of record the rejection is maintained.

***Conclusion***

In light of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, Stephen R. Albainy-Jenei at (513) 651-6839 or salbainyjenei@fbtlaw.com.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

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By _____

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